IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

ANNIE TUMMINO, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 12-CV-763
MARGARET HAMBURG, Commissioner of Food and Drugs, *et al.*,	)	(Korman, J.) (Pohorelsky, M.J.)
Defendants.	)	

ANSWER TO FIRST AMENDED SUPPLEMENTAL COMPLAINT

Defendants, Margaret Hamburg, in her official capacity as Commissioner of Food and Drugs, and Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, hereby answer Plaintiffs' First Amended Supplemental Complaint as follows:

1. This paragraph contains characterizations of this lawsuit and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that Plaintiffs challenge Defendants' actions as arbitrary and capricious under 5 U.S.C. § 706(2)(A).

2. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

3. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

4. Denied except to admit that the Court's March 2009 order granted Plaintiffs' motion for summary judgment in part and vacated the FDA's denial of the citizen petition.

Defendants deny any characterization of that order, which speaks for itself, and respectfully refer the Court to that order for a complete and accurate statement of its contents.

5. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

6. This paragraph contains characterizations of this lawsuit and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that Plaintiffs seek declaratory and injunctive relief.

I. Parties

7–8. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in these paragraphs.

9. Defendants admit that Margaret A. Hamburg is Commissioner of Food and Drug and is sued in her official capacity, and that Andrew C. von Eschenbach is no longer acting Commissioner. Defendants further admit that the remainder of this paragraph paraphrases a portion of FDA's website. Defendants deny any characterization of that website, which speaks for itself, and respectfully refer the Court to that website for a complete and accurate statement of its contents. *See* http://www.fda.gov/aboutfda/whatwedo/default.htm (last visited May 22, 2012).

10. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that Kathleen Sebelius is Secretary of Health and Human Services and is sued in her official capacity, and that, in a memorandum dated December 7, 2011, the Secretary stated that the "Federal Food, Drug, and Cosmetic Act provides that '[t]he Secretary [of Health and Human

Services], through the Commissioner, shall be responsible for executing' its provisions." Defs.' Resp. to Order to Show Cause, Ex. E at 2 (citing 21 U.S.C. § 393(d)(2)). Defendants deny any characterization of that memorandum, which speaks for itself, and respectfully refer the Court to that memorandum for a complete and accurate statement of its contents.

II. Factual Allegations

11. Admitted.

12. Defendants admit that the Plan B sponsor filed an SNDA seeking a full OTC switch in 2003 and filed amended SNDAs seeking a partial OTC switch in 2004 and 2006.

13. Defendants deny that FDA ever concluded that the citizen petition was supported by sufficient data or other information.

14. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

15. With respect to the first sentence, Defendants admit that, in a letter dated June 9, 2006, FDA denied the citizen petition because it was not supported by sufficient data or other information. Defendants deny any characterization of that letter, which speaks for itself, and respectfully refer the Court to that letter for a complete and accurate statement of its contents. The second sentence is denied except to admit that, in response to the SNDA filed by the Plan B sponsor in 2003, the FDA issued a Not-Approvable letter in May 2004.

16. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that, in 2006, FDA approved an amended SNDA submitted by the Plan B sponsor to allow the distribution of Plan B without a prescription to adults 18 and over, while the product

remained prescription-only for those under 18.

17. This paragraph contains characterizations of this lawsuit and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that Plaintiffs filed this lawsuit in 2005. Plaintiffs' complaint speaks for itself, and Defendants respectfully refer the Court to that complaint for a complete and accurate statement of its contents.

18–22. These paragraphs contain argument and characterizations of the Court's March 2009 order, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants admit that the Court's March 2009 order vacated the FDA's denial of the citizen petition and "remanded to the FDA to reconsider its decisions regarding the Plan B switch to OTC use." *Tummino v. Torti*, 603 F. Supp. 2d 519, 550 (E.D.N.Y. 2009). Defendants deny any characterization of that order, which speaks for itself, and respectfully refer the Court to that order for a complete and accurate statement of its contents.

23. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit, with respect to the first sentence, that by letter dated April 21, 2009, FDA informed the sponsor that Plan B could be made available to women age 17 and over without a prescription upon the submission and approval of appropriate labeling changes.

24. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

25. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except

to admit that FDA determined that the actual use and labeling comprehension studies submitted by the Plan B One-Step sponsor could not be applied to support the citizen petition.

26. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

27. This paragraph contains argument and hypothetical conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

28. This paragraph contains argument and hypothetical conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that while granting the citizen petition would trigger the beginning of notice-and-comment rulemaking, it would not assure that any rule would result.

29. This paragraph contains argument and hypothetical conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that, where applicable, 21 U.S.C. §§ 355(c)(3)(E)(iii) and 355(j)(5)(F)(iii) provide limited three-year periods of marketing exclusivity. Defendants deny any characterization of those statutory provisions, which speak for themselves, and respectfully refer the Court to the provisions for a complete and accurate statement of their contents.

30. This paragraph contains argument, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that Plaintiffs initiated contempt proceedings.

31. Admitted.

32. Denied except to admit that, beginning before the Court's March 2009 order,

FDA review staff and the Plan B One-Step sponsor communicated with respect to the type and design of studies to support a full OTC switch.

33. The first sentence is denied except to admit that FDA review staff and the Plan B One-Step sponsor communicated with respect to the type and design of studies to support a full OTC switch, and that the authors of articles describing the Plan B One-Step actual use and labeling comprehension studies analyzed data from a total of 675 females between the ages of 12 and 17 who enrolled in those studies. The second sentence characterizes the conclusions reached by the authors of articles describing the Plan B One-Step actual use and labeling comprehension studies. Defendants deny any characterization of those articles, which speak for themselves, and respectfully refer the Court to those articles for a complete and accurate statement of their contents.

34. The first sentence contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied. The second sentence characterizes the conclusions reached by the authors of an article describing the Plan B One-Step actual use study. Defendants deny any characterization of that article, which speaks for itself, and respectfully refer the Court to that article for a complete and accurate statement of its contents.

35. Defendants admit that, on December 7, 2011, the Commissioner issued a statement announcing that FDA had completed its review of the Plan B One-Step SNDA. Defendants deny any characterization of that statement, which speaks for itself, and respectfully refer the Court to that statement for a complete and accurate statement of its contents.

36. Defendants admit that, on December 7, 2011, the Secretary issued a memorandum

that includes the quoted text. Defendants deny any characterization of that memorandum, which speaks for itself, and respectfully refer the Court to that memorandum for a complete and accurate statement of its contents.

37. Defendants admit that, on December 7, 2011, the Secretary issued a statement that includes the quoted text. Defendants deny any characterization of that statement, which speaks for itself, and respectfully refer the Court to that statement for a complete and accurate statement of its contents.

38. Admitted. Defendants further aver that it is both proper and commonplace for federal agencies to communicate with White House staff before announcing decisions on matters of great public interest.

39. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

40. With respect to the first sentence, Defendants admit that actual use studies are designed to assess specific aspects of consumer use of a drug product in an OTC setting. The second and third sentences contain argument and conclusions of law, not allegations of fact, and thus no response is required.

41. This paragraph contains argument, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that in some instances FDA has extrapolated data on adults to the pediatric population when FDA has determined that such extrapolation was appropriate.

42. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except

to admit that certain office directors have the delegated authority to approve an SNDA seeking an OTC switch.

43. Defendants admit that decisions regarding routine OTC switches are not normally discussed with the White House, but deny that it is unusual or improper for federal agencies to communicate with White House staff before announcing decisions on matters of great public interest.

44. This paragraph contains argument and vague characterizations of FDA review practices, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny any characterization of FDA's review practices.

45. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

46. Denied except to admit that FDA again denied the citizen petition on December 12, 2011.

47. The first sentence of this paragraph contains characterizations of the Court's March 2009 order, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants admit that the Court's March 2009 order stated that, on remand, FDA could be "trusted to conduct a fair assessment of the scientific evidence." *Tummino*, 603 F. Supp. 2d at 549. Defendants deny any characterization of that order, which speaks for itself, and respectfully refer the Court to that order for a complete and accurate statement of its contents. The second sentence is denied.

48. Defendants admit that, on December 12, 2011, FDA issued a letter denying the citizen petition that contains the quoted text. Defendants deny any characterization of that

letter, which speaks for itself, and respectfully refer the Court to that letter for a complete and accurate statement of its contents.

49. Denied except to admit that, beginning before the Court's March 2009 order, FDA review staff and the Plan B One-Step sponsor communicated with respect to the type and design of studies to support a full OTC switch.

50. Denied.

51. With respect to the first sentence, Defendants admit that, on December 12, 2011, FDA issued a letter denying the citizen petition. Defendants deny any characterization of that letter, which speaks for itself, and respectfully refer the Court to that letter for a complete and accurate statement of its contents. The second sentence contains argument and characterizations of the Court's March 2009 order, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants deny any characterization of that order, which speaks for itself, and respectfully refer the Court to that order for a complete and accurate statement of its contents.

52–55. These paragraphs contain argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

56. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that FDA cannot approve an OTC switch unless the evidence demonstrates that prescription-dispensing requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and that the drug is safe and effective for use in

self-medication as directed in proposed labeling. *See* 21 U.S.C. § 353(b)(1), (3); 21 C.F.R. § 310.200(b).

57. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

58. Denied except to admit that FDA has twice denied the citizen petition because it was not supported by sufficient data or other information.

59. This paragraph contains argument, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that the data necessary to meet the statutory and regulatory standards for approval will vary from product to product, depending on, among other things, whether the efficacy and safety of OTC use can be shown by prior OTC approval or an established monograph, whether there is a new OTC indication, whether there is a new method of use for the OTC drug, whether there is a new OTC warning, whether there are new OTC medical follow-up recommendations, and whether there are specific concerns about self-medication.

60. This paragraph contains argument, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in this paragraph because those allegations are set forth in vague, undefined terms.

61. This paragraph contains argument, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

62. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

63. With respect to the first sentence, Defendants admit that the currently marketed levonorgestrel-based emergency contraceptives — Plan B One-Step, Next Choice, and Perrigo R&D's "levonorgestrel tablets, 0.75 mg" — are available OTC to women 17 and over, and by prescription only to women under 17. With respect to the second sentence, Defendants admit that Next Choice and Perrigo R&D's "levonorgestrel tablets, 0.75 mg" are generic equivalents of Plan B. The third and fourth sentences are admitted.

64. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

65. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

66. Denied except to admit that an article describing the referenced study was published in the January 2012 issue of the Journal of the American Medical Association. *See* Tracey A. Wilkinson et al., *Access to Emergency Contraception for Adolescents*, 307 J. Am. Med. Ass'n 362-63 (2012). Defendants deny any characterization of that article, which speaks for itself, and respectfully refer the Court to that article for a complete and accurate statement of its contents.

67. This paragraph contains argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied except to admit that the majority of women who use emergency contraception are adults.

68–70. These paragraphs contain argument and conclusions of law, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, denied.

III. Causes of Action

FIRST CAUSE OF ACTION: ARBITRARY AND CAPRICIOUS

71. Defendants restate and incorporate by reference the responses contained in all preceding paragraphs.

72. Denied.

SECOND CAUSE OF ACTION: EXCEEDS STATUTORY AUTHORITY

73. Defendants restate and incorporate by reference the responses contained in all preceding paragraphs.

74. Denied.

THIRD CAUSE OF ACTION: RIGHT TO PRIVACY

75. Defendants restate and incorporate by reference the responses contained in all preceding paragraphs.

76. Denied.

FOURTH CAUSE OF ACTION: EQUAL PROTECTION

77. Defendants restate and incorporate by reference the responses contained in all preceding paragraphs.

78–79. Denied.

FIFTH CAUSE OF ACTION: INFORMATIONAL PRIVACY

80. Defendants restate and incorporate by reference the responses contained in allpreceding paragraphs.

81. Denied.

IV. Prayer for Relief

The remaining paragraphs of the First Amended Supplemental Complaint contain a Prayer for Relief, to which no response is required. To the extent a response is deemed necessary, Defendants deny the allegations contained in the Prayer for Relief, and further aver that Plaintiffs are not entitled to the requested relief or any other relief from Defendants.

Defendants deny any and all allegations in the First Amended Supplemental Complaint not expressly admitted herein to which a response is deemed required.

DEFENSES

1. This Court lacks subject matter jurisdiction over this action.

2. The First Amended Supplemental Complaint fails to state a claim for which relief can be granted.

3. Defendants' actions did not violate the U.S. Constitution, the Administrative Procedure Act, the Federal Food, Drug, and Cosmetic Act, or any other statutory or regulatory provision.

CONCLUSION

WHEREFORE, having fully answered, Defendants respectfully request that the Court enter judgment dismissing this action with prejudice and awarding Defendants costs and such other relief as the Court may deem appropriate.

Dated: May 22, 2012

Respectfully submitted,

Of Counsel:

STUART F. DELERY
Acting Assistant Attorney General

DAVID J. HOROWITZ
Deputy General Counsel

LORETTA E. LYNCH
United States Attorney

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

SCOTT A. KAPLAN
Assistant Chief Counsel
U.S. Department of Health & Human Services
Office of General Counsel
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Eastern District of New York

IAN HEATH GERSHENGORN
Deputy Assistant Attorney General

SHEILA LIEBER
Deputy Director, Federal Programs Branch

F. FRANKLIN AMANAT
Assistant United States Attorney
271 Cadman Plaza East, 7th Floor
Brooklyn, NY 11201-1820
Telephone: (718) 254-6024

/s/ *Eric B. Beckenhauer*
ERIC B. BECKENHAUER
Cal. Bar No. 237526
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave. NW
Washington, DC 20530
Telephone: (202) 514-3338
Facsimile: (202) 616-8470
E-mail: eric.beckenhauer@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2012, the foregoing document was filed with the Clerk of Court via the CM/ECF system, causing it to be served on Plaintiffs' counsel of record.

/s/ *Eric B. Beckenhauer*
ERIC B. BECKENHAUER